

WEDNESDAY, SEPTEMBER 22, 2010, 3:30 PM – 5:30 PM

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debris retrieved in all cases with Fibernet, 43% with other filters. Mean debris surface area: Fibernet 63,8 mm², other filters 12,2 mm². Number of particles < 100µ: 4976 with Fibernet, 2752 with other filters.

-12 renal angioplasties. Technical success: 100%. No complication. All samples visually contained significant emboli. Mean debris surface area: 106 mm², debris in the filter: 24 mm². Mean number of particles 28-60µ: 2136 +/- 776. and > 60µ: 5918 +/- 1362. At 6 month follow-up no deterioration of the renal function.

-2 vertebral angioplasties. Visible debris removed in the 2 patients. Mean debris area: 184 mm². (aspirated debris: 114 mm², debris in the filter 70 mm²) (Comparable results as in carotid angioplasty).

-3 femoropopliteal angioplasties for chronic occlusion. Visible debris removed in the 3 patients. 2 filters totally blocked. Mean debris area: 191 mm²

Conclusion: The Fibernet EPD is easy to use and very efficient. Visible debris are removed in all patients. It allows for capture of particles < 100µ without compromising the flow. It could be used in any vessels.

Chronic Total Occlusions

143C

Wednesday, September 22, 2010, 3:30 pm – 5:30 pm

(Abstract Nos 25-32)

TCT-25

Percutaneous Coronary Angioplasty of Chronic Total Occlusion. Is There a Learning Curve?

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Purpose: Percutaneous coronary angioplasty (PCI) of Coronary Chronic Total Occlusions (CTO) is still associated with a reduced success rate. Lesion- and patient- related factors of failure are well known, but the influence of operator experience influence has been less described. The purpose of this abstract is to describe the influence of the operator and known predictive factors on the success rate of CTO PCI (European CTO club definition) treated by several operators in our institution.

Methods: The study included 1,000 consecutive CTO PCI performed between Jan2004 and Dec 2009 by 13 operators. In order to assess the learning curve, an index of individual operator experience during the study was defined as 1 for the first 50 cases, 2 for next fifty, up to 6 for operators with > 250 cases. PCI performed by the 2 main operators were compared with 11 others.

Results: A multivariate logistic regression analysis was performed in the whole population using all factors with a p value <0.2 by univariate analysis. Previous CABG (OR 0.44; p= 0.015), no visible stump (OR 0.61; p= 0.031), calcifications (0-3)(OR 0.78; p= 0.009) and the occlusion length (OR 0.98; p= 0.000; 2% failure for each mm of occlusion length) were found to be independent predictors of failure. The operator's experience was a predictor of success (OR 1.24; p= 0.002) but the year of treatment in the whole group was not. Here are the success rates and predictors value in patients treated by 2 main operators and others.

	2 main operators	Other operators (n=11)	p
CTO's n=	542	458	
Success rate (%)	72.2	66.6	0.013
Experience	4.17 ± 1.58	1.35 ± 0.55	0.000
Previous CABG (%)	10.0	4.4	0.004
No visible stump (%)	29.2	18.3	0.011
Calcifications (0-3)	1.07 ± 1.02	0.96 ± 1.0	0.072
Occlusion length (mm)	23.2 ± 18.0	19.8 ± 15.9	0.039

Conclusion: Individual experience of the operator but not of the whole team is a strong predictor of CTO PCI success despite a higher incidence of predictors of failure.

TCT-26

The Impact of Percutaneous Coronary Intervention for CTO Lesions and Contrast Media on Renal Function

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Background: Improvements in the technique and success rates of percutaneous coronary intervention (PCI) for chronic total occlusions (CTOs) have resulted in an increase in the complexity of PCI. Contrast media volume, one of the major risk factors for contrast-induced nephropathy (CIN), represents an extremely important concern in the management of patients with CTO lesions. The aim of this study was to evaluate the impact of CTO procedures and contrast media use on renal function.

Methods: We evaluated in-hospital, procedural outcomes related to renal function in 425 consecutive patients who underwent PCI for CTOs of > 3 months in duration between April 2006 and March 2009 compared to the non-CTO control group (n=XXXX), reporting baseline and 48 h postprocedural creatinine levels. CIN is defined as an absolute (≥0.5 mg/dl) or relative (≥25%) increase in serum creatinine levels compared to baseline values after exposure to contrast media in the absence of alternative explanations for renal impairment.

Results: In 425 consecutive CTO patients (mean age, 65.5 ± 11.0 yrs; 83.3% male), the average total amount of contrast media administered was significantly higher than non-CTO control group (328.6 ± 163.1 ml vs. 194.6 ± 112.7 ml, p<0.0001). Serum creatinine level after the procedure was also significantly higher in CTO patient than in non-CTO patient (0.95 ± 0.28 mg/dl vs. 0.91 ± 0.33 mg/dl, p=0.05). CIN occurred in 10.8% (46/425) of the CTO group and 6.7% (57/850) of the non-CTO group (p=0.02). Patients who developed CIN were older (70.0 ± 9.9 yrs. vs. 65.0 ± 10.9 yrs., p=0.0016), had longer fluoroscopy time (75.2 ± 47.0 min vs. 51.7 ± 35.0 min, p=0.0001) and received a higher amount of contrast media (424 ± 212 ml vs. 326 ± 151 ml, p<0.00001) than those who did not develop CIN in the CTO group. Multivariate logistic regression analysis revealed that significant predictors of CIN were

age (OR 2.8, 95%CI 1.025-1.140) and contrast volume (OR 3.0, 95%CI 1.004-1.006). Of 46 patients who developed CIN, 38 patients (82.6%) experienced a recovery of their renal function at 1 month, with no patients requiring dialysis during that time.

Conclusions: The incidence of CIN following CTO-PCI was significantly higher than that following Non-CTO-PCI. To prevent CIN, careful attention should be paid to identifying patients at risk for the condition and minimizing the amount of contrast media used in these patients during CTO procedures.

TCT-27

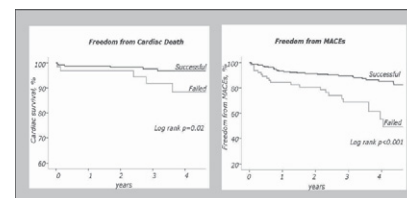
Improved Cardiac Survival and Quality of Life after Successful Percutaneous Recanalisation of Coronary Artery Chronic Total Occlusions: a Single-Centre Experience

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Background: We sought to compare the effects of a successful chronic total occlusion (CTO) recanalisation on long-term cardiac survival and angina-related quality of life compared to failed procedure.

Methods: CTO was defined as a native coronary artery occlusion with duration >3 months and TIMI flow 0. Primary end-points were cardiac death and MACEs, defined as cardiac death, MI and target vessel revascularisation at follow-up. The SAQ-UK questionnaire was used to assess angina-related quality of life before and after CTO recanalisation procedure.

Results: Among 302 consecutive patients, 78% underwent successful CTO recanalisation while in 22% patients the procedure failed. Multivariate predictors of unsuccessful procedure were moderate-severe vessel calcification (OR 3.61;95%CI 1.53-8.52; p<0.01), CTO length >20 mm (OR 2.64;95%CI 1.18-5.88; p=0.01) and CTO duration >12 months (OR 3.01;95%CI 1.15-6.91; p=0.02). Median follow-up was 3.4 years, during which 15 patients had a cardiac death. When compared with successful procedure, failed CTO recanalisation was associated with a significant higher risk of cardiac death (HR 5.01;95%CI 1.29-19.4; Log-rank p=0.02), and MACEs (HR 4.7;95%CI 2.37-9.6; Log-rank p<0.001). These results were confirmed by Cox proportional hazard analysis for survival, after adjustment for age, previous MI and LV ejection fraction. By SAQ-UK questionnaires, patients with successful CTO recanalisation experienced fewer physical activity limitations, rarer angina episodes and higher quality of life at longer follow-up (all p<0.05) when compared to patients with failed procedure.



Conclusions: Successful percutaneous CTO recanalisation improved long-term cardiac survival, reduced major adverse cardiac events and improved the angina-related quality of life compared to failed procedure.

TCT-28

Long-Term Clinical Safety and Efficacy of Drug-Eluting Stents for the Treatment of Chronic Total Occlusions: Report from a Multi-National 763 Patient Registry

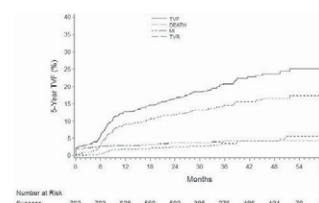
Roxana Mehran¹, Bimmer E Claessen¹, Cosmo Godino², Kotaro Obunai¹, George Dangas¹, Mauro Carlino², Young-Hak Kim³, Carlo Di Mario⁴, Seung-Jung Park³, Gregg W. Stone¹, Antonio Colombo², Jeffrey Moses¹, Martin B. Leon¹

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Background: Drug-eluting stents (DES) are widely used in the treatment of CTOs, even though long-term safety and efficacy data are currently lacking.

Methods: Between 2002 and 2009, 763 patients with 795 CTO were treated with DES at four tertiary care centers in the US, the UK, Italy and South Korea. Long term follow-up was obtained for all patients by office visit or telephone interview. The primary clinical endpoint was target vessel failure (TVF, composite of death, myocardial infarction [MI] and target vessel revascularization [TVR]). The primary safety endpoint was definite/probable stent thrombosis up to five-year follow-up.

Results: Mean age was 61 ± 11 years, 28% of patients had diabetes mellitus, 36% had prior myocardial infarction and 12.7% had prior CABG, mean LVEF was 54 ± 10%. The CTO location was the left anterior descending coronary artery in 37% of patients, circumflex coronary artery in 21%, and right coronary artery in 42%. The mean lesion length was 24 ± 16 mm; a mean of 1.9 ± 0.9 stents were implanted per patient; mean stent length was 48 ± 24 mm. Sirolimus-eluting stents (SES) were used in 73% of patients, and paclitaxel-eluting stents (PES) in 27%. The median follow-up duration was 2.8 years (interquartile range 2.0-3.8 years). Kaplan-Meier estimates for five-year all-cause death, MI, TVR and TVF were 5.6%, 2.5%, 17.4%, and 24.0%, respectively (Figure). Of note, there was a linear rate of late (>1 year) TVR events (2.1% per annum). At five years, 9 patients (1.5%) had a definite/probable stent thrombosis of which 5 (0.8%) occurred after one year.



Conclusion: In this large prospective registry, PES and SES were safe and efficacious in the treatment of CTOs. Although a linear rate of late TVR (2% annually) was found, the low rate of stent thrombosis in this complex lesion subset is notable.

TCT-29

Long-Term Clinical Outcomes after Percutaneous Coronary Intervention with Drug-eluting Stents versus Bare Metal Stents for Chronic Total Occlusions: Two-Year Outcomes from a 1,781 Patient Multi-National Registry

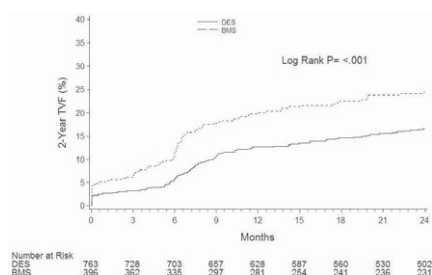
Bimmer E Claessen¹, Roxana Mehran¹, Cosmo Godino², Kotaro Obunai³, George Dangas⁴, Mauro Carlino⁵, Young-Hak Kim⁶, Carlo DiMario⁷, Seung-Jung Park⁸, Gregg W. Stone⁹, Antonio Colombo¹⁰, Martin B. Leon¹¹, Jeffrey W. Moses¹², On Behalf of The Multinational CTO Registry

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Background: Percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) is associated with high restenosis rates. The effectiveness of drug-eluting stents (DES) for CTO has only been tested in one small randomized trial.

Methods: Between 1998 and 2009, a total of 1,781 patients with 1,846 CTO underwent PCI at four centers in the US, UK, Italy and South Korea. We compared patients treated with DES (paclitaxel-eluting stents [PES] or sirolimus-eluting stents [SES]) and bare metal stents (BMS). The primary endpoint was target vessel failure (TVF, composite of death, myocardial infarction [MI] and target vessel revascularization [TVR]). The primary safety endpoint was definite/probable stent thrombosis up to five-year follow-up.

Results: Procedural success (residual stenosis <30% and TIMI flow ≥2) was obtained in 1,222 (69%) patients. Stents were implanted in 1159 patients. A total of 396 patients (34%) received BMS and 763 patients (66%) received DES (73% SES, 27% PES). When compared with BMS-treated patients, DES-treated patients more often had diabetes mellitus, hypertension, smoking, hyperlipidemia and chronic kidney disease, and less often had prior MI. Median follow-up duration was 1080 days. Kaplan-Meier estimates for two-year TVF were 15.8% with DES vs. 24.4% with BMS ($p<0.01$). TVR was significantly lower in the DES group (12.1% vs. 20.6%, $p<0.01$). The incidence of death (2.5% vs. 2.4%, $p=0.83$), MI (1.9% vs. 1.2%, $p=0.42$) or definite/probable stent thrombosis (1.4% vs. 0.9%, $p=0.46$) was similar between both groups. By multivariable analysis, DES use was a significant independent predictor of freedom from TVR (HR 0.60, 95% CI 0.45-0.79, $p<0.01$).



Conclusion: In this large multicenter CTO registry, SES and PES compared with BMS use were associated with a significant reduction in TVF and TVR, with a comparable long-term safety profile.

TCT-30

Predictors of Success to Open a Coronary Chronic Total Occlusion. Insight From a Prospective Registry of 1,000 Consecutive Cases

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Purpose: Percutaneous coronary angioplasty (PCI) of coronary Chronic Total Occlusions (CTO) is still associated with a reduced success rate. Predictors of angiographic failure have been identified mainly by specialized Japanese operators with a very high success rate. The purpose of this study is to identify the predictors of success in a large population of patients with CTO's (European CTO Club definition) treated by several operators in our institution.

Methods: The study included 1,000 consecutive CTO PCI performed between Jan 2004 and Dec 2009 by 13 operators. In order to assess the learning curve, an index of individual operator experience during the study was defined as 1 for the first 50 cases, 2 for next fifty, up to 6 for operators with > 250 cases.

Results: Pts were 63 ± 12 yrs old, 25.1 % diabetics. LAD was the target lesion in 30.6 %. Lesion length was 20.8 ± 17.1 mm, tortuosity index 0.17 ± 0.38/1, calcification index 1.01 ± 1.01/3 and bridging collaterals 35.2%. The overall angiographic success rate was 70.1%. By univariate analysis, predictors of success were a lower weight or body mass index, no previous smoking, no myocardial infarction or CABG, visible stump, tapering morphology, bifurcation, no proximal tortuosity, more homolateral collaterals, lower calcification score, shorter occlusion length and broader operator experience. Conversely, time periods of the study were not found as predictors of success. Results of the multivariate analysis for predictors of success are summarized in the table below.

	OR	p	95% CI
Previous CABG	0.44	0.015	0.23-0.86
Former smoker	0.60	0.017	0.39-0.91
No visible stump	0.61	0.031	0.39-0.96
Calcifications (0-3)	0.78	0.009	0.65-0.94
Occlusion length (mm)	0.98	0.000	0.97-0.99
Operator experience (1-6)	1.24	0.002	1.08-1.42

Conclusion: In this real world study, the strongest lesion-related predictors of failure are: no visible stump, calcification score and occlusion length (2% failure for each mm of occlusion

length). These factors might be used to define a predictive score of failure. Operator experience (identified for the first time) is also a strong predictor of success.

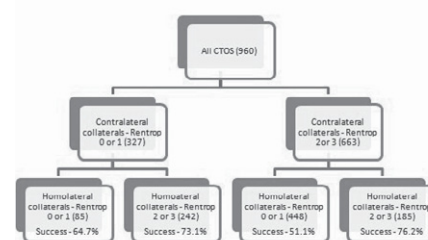
TCT-31

An Assessment of the Presence of Collateralisation as a Predictor of Angiographic Success Rates of Percutaneous Coronary Intervention in Chronic Total Occlusions

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Background: Chronic total occlusions (CTO's) represent the most challenging lesions for percutaneous coronary intervention (PCI). **Aim:** We sought to clarify the importance of contralateral (contra) and homolateral (homo) collaterals as a predictor of angiographic success. **Methods:** All patients treated with PCI for CTO's (European CTO club definition) in our institution were prospectively entered in a dedicated database (2004-2009). The presence of contra and homo collaterals were assessed by a senior interventionalist and classified according to the Rentrop criteria. Patients were divided into 2 groups based on the presence of contra collaterals classified as poor (Rentrop grade 0-1) or good (grade 2-3). They were further subdivided into 2 groups according to the presence of poor or good homo collaterals. We additionally looked at the use and role of contra injection according to the collaterals grade. **Results:** 960 patients, aged 63.1 ± 11.6 years were studied. Baseline demographics were similar in the 4 groups. As shown in the figure, there was no difference in success rates based on the presence or absence of good contra collaterals ($p=0.65$). But in patients with good contra collaterals, additional homo collaterals was associated with an increased rate of success ($p=0.01$). In patients with poor contra collaterals, there was no difference in angiographic success if contra injection was used or not (72.4 vs. 59.5%, $p=0.14$). Same results were observed in patients with good contra collaterals (71.8 vs. 66.7%, $p=0.17$).



Conclusion: Well established contralateral collaterals are not associated with an increase in angiographic success even when a bilateral approach is used. Having good homolateral collaterals appears to be a better predictor of success.

TCT-32

Impact of Target Vessel on Long-Term Survival after Percutaneous Coronary Intervention for Chronic Total Occlusions: Two-Year Outcomes from a 1,781 Patient Multi-National Registry

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Background: A recent study suggested that successful percutaneous coronary intervention (PCI) of a chronic total occlusion (CTO) in the left anterior descending (LAD), but not in the left circumflex (LCX) or right coronary artery (RCA) was associated with improved survival. This study aims to validate these results in a large contemporary cohort of CTO patients treated with PCI.

Methods: Between 1998 and 2009, a total of 1,781 patients underwent PCI of a CTO at four tertiary care centers in the US, the UK, Italy and South Korea. Patients with CTOs in multiple target vessels were excluded ($n=65$, 3.6%). Follow-up was performed by telephone interview at 30 days, and yearly thereafter. Long term mortality was compared between patients with successful vs. unsuccessful PCI stratified by target vessel.

Results: Procedural success (residual stenosis <30% and TIMI flow ≥2) was obtained in 72% (429/590) of LAD patients, 70% (298/425) of LCX patients and 66% (504/767) RCA patients. Compared with RCA and LCX patients, LAD patients were less often male, and less often had a history of previous coronary artery bypass surgery. Compared with LAD and RCA patients, LCX patients more often had diabetes mellitus. Median follow-up duration was 1080 days. Kaplan-Meier estimates of mortality rates at 2-year follow-up were 3.6 vs. 9.9% ($p<0.01$), 1.7% vs. 7.3% ($p<0.01$), and 2.1% vs. 2.5% ($p=0.74$) in successful vs. unsuccessful LAD, LCX and RCA patients, respectively (figure).